PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Shinichiro KUROSAWA and
Deborah J. Stearns-KUROSAWA

Serial No.: 10/028,741

Filed: December 20, 2001

For: METHOD FOR MONITORING COAGULABILITY AND HYPERCOAGULABLE STATES

Group Art Unit: 1641

Examiner: C. Kaufman

Atty. Dkt. No.: OMRF:004US

CERTIFICATE OF MAILING
37 C.F.R 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Box DD, Commissioner for Patents, Washington, DC 20231, on the date below:

March 16, 2004
Date

Steven L. Highlander

AMENDMENT AND REQUEST FOR RECONSIDERATION UNDER 37 C.F.R. §1.111

Commissioner for Patents
P.O. 1450
Alexandria, VA 22213-1450

Sir:

This is in response to the Office Action mailed on January 8, 2004, to which a response is due on April 8, 2004. No fees are believed to be due in connection with the filing of this response; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Fulbright & Jaworski Deposit Account No.: 50-1212/OMRF:004US.

Amendments begin on page 2; **Remarks** begin at page 4.

AMENDMENTS

Listing of Claims

The following listing of claims replaces all previous listings or versions thereof:

1. (Presently amended) A method for monitoring effective thrombin levels in ~~patients~~a human patient undergoing anticoagulant therapy comprising measuring circulating levels of soluble endothelial protein C receptor (sEPCR) of said patient, wherein lowered sEPCR levels relate to lowered effective thrombin activity.

2. The method of claim 1, wherein the anticoagulant therapy involves a vitamin K antagonist.

3. The method of claim 1, wherein the anticoagulant therapy involves at least one of Warfarin, Coumadine, Previscan, and Sintrom.

4. The method of claim 1, wherein the anticoagulant therapy involves use of heparin, low molecular weight heparin, pentasaccharides, hirudin, hirudin analogs, coagulation factor inhibitors, protein C pathway components, tissue factor pathway inhibitors, anti-platelet compounds or fibrinolytic pathway components.

5. The method of claim 1, wherein the sEPCR is measured by an immunoassay.

6. The method of claim 5, wherein the sEPCR is measured by ELISA.

7. The method of claim 1, wherein the sEPCR level is determined by measuring sEPCR in a blood product, cerebrospinal fluid or urine.

8. The method of claim 7, wherein the blood product is plasma or serum.

9. (Presently amended) A method for monitoring effectiveness of anticoagulant therapy in a human patient comprising measuring circulating sEPCR levels of said patient, wherein decreases in sEPCR indicate that the anticoagulant therapy is effective.

10. The method of claim 9, wherein the anticoagulant therapy involves a vitamin K antagonist.

11. The method of claim 9, wherein the anticoagulant therapy involves at least one of Warfarin, Coumadine, Previscan, and Sintrom.

12. The method of claim 9, wherein the anticoagulant therapy involves use of heparin, low molecular weight heparin, pentasaccharides, hirudin, hirudin analogs, coagulation factor inhibitors, protein C pathway components, tissue factor pathway inhibitors, anti-platelet compounds or fibrinolytic pathway components.

13. The method of claim 9, wherein the sEPCR is measured by an immunoassay.

14. The method of claim 13, wherein the sEPCR is measured by ELISA.

15. The method of claim 9, wherein the sEPCR level is determined by measuring sEPCR in a blood product, cerebrospinal fluid or urine.

16. The method of claim 15, wherein the blood product is plasma or serum.

17-30. (Canceled)